MedSun Newsletter #62, July 2011

Articles

Silicone Gel-Filled Breast Implants: Updated Safety Information

Print Item
E–mail Item

FDA Consumer Update

FDA has released a report that includes preliminary safety data from follow-up studies conducted on the long-term performance and safety of silicone gel-filled breast implants. Almost five years later, FDA's report continues to support the safety and effectiveness of these implants when used as intended, but states that women should fully understand the risks before considering getting them.

Additional Information:

FDA Consumer Update. Silicone Gel-Filled Breast Implants: Updated Safety Information. June 22, 2011.
http://www.fda.gov/ForConsumers/ConsumerUpdates/ucm259825.htm[7]

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Boston Scientific Innova Self-Expanding Stent System: Recall - Failure to Deploy

Print Item
E–mail Item

FDA MedWatch Safety Alert

Complaints of no deployment and partial deployment have been received. This type of failure may result in vessel wall injury, increased procedure time and/or emergency surgery to remove the partially deployed stent. This recall does not affect stents that have already been implanted as the issue occurs during delivery of the stent.

Additional Information:

FDA MedWatch Safety Alert. Boston Scientific Innova Self-Expanding Stent System: Recall - Failure to Deploy. June 17, 2011.
http://www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm259764.htm[9]

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American Regent Initiates Voluntary Nationwide Recall of Concentrated Sodium Chloride Injection, USP, 23.4%, 30 mL Single

Print Item
E–mail Item

Dose Vial Due to Particulates

American Regent Press Release

This voluntary recall was initiated because some of the vials of this lot contain visible particulates. Potential adverse events after intravenous administration of solutions containing particulates may include disruption of blood flow within small blood vessels in the lung, localized inflammation (swelling and redness due to accumulation of inflammatory cells), and granuloma formation. American Regent is undertaking this voluntary recall in consideration of the potential for safety issues if these lots of product are administered to patients.

Additional Information:

American Regent Press Release. American Regent Initiates Voluntary Nationwide Recall of Concentrated Sodium Chloride Injection, USP, 23.4%, 30 mL Single Dose Vial Due to Particulates. June 15, 2011.
http://www.fda.gov/Safety/Recalls/ucm259312.htm[11]

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Boston Scientific iCross and Atlantis SR Pro 2 Coronary Imaging Catheters: Recall - Catheter Tip Can Break Inside of the Patient

Print Item
E–mail Item

FDA MedWatch Safety Alert

The catheter tip can break inside of the patient and embolize causing tissue and blood vessel injury, heart attack or other serious events requiring additional unplanned surgery. Boston Scientific Corporation notified customers by letter on May 27, 2011 describing the problem, the potential hazard, and the action to be taken. Customers were instructed to discontinue use and return all products to Boston Scientific.

Additional Information:

FDA MedWatch Safety Alert. Boston Scientific iCross and Atlantis SR Pro 2 Coronary Imaging Catheters: Recall – Catheter Tip Can Break Inside of the Patient. June 14, 2011.
http://www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm259097.htm[13]

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Terumo Coronary Ostia Cannula 10, 12, 14 Fr: Recall - Fragments of Adhesive and Plastic in the Cannula Tip May Embolize

Print Item
E–mail Item

FDA MedWatch Safety Alert

Foreign fragments of adhesive and plastic in the cannula tip may embolize causing arterial injury, hemorrhaging or other serious events requiring unplanned surgery. Terumo

Cardiovascular Systems Corporation (Terumo CVS) decided to remove the product line from the market and discontinue further supply. Terumo is advising customers to immediately discontinue use of any affected product and return all products in inventory.

Additional Information:

FDA MedWatch Safety Alert. Terumo Coronary Ostia Cannula 10, 12, 14 Fr: Recall – Fragments of Adhesive and Plastic in the Cannula Tip May Embolize. June 14, 2011. http://www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm259082.htm[15]

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Maquet Datascope Corp. Intra-Aortic Balloon Pumps: Recall - Shuts Off Without Warning

Print Item
E–mail Item

FDA MedWatch Safety Alert

Defective fan in the power supply may cause overheating and shut down the device without visible or audible alarms. Consequences of unanticipated interruption of therapy may include the inability to decrease already-present ischemia, thrombus formation, organ injury or other serious events. Maquet Datascope Corporation notified customers by letter on March 17, 2011 describing the problem, the potential hazard, and the action to be taken. Customers were advised that their Service Representative would arrange to replace the power supply on affected devices which would contain a new fan assembly.

Additional Information:

FDA MedWatch Safety Alert. Maquet Datascope Corp. Intra-Aortic Balloon Pumps: Recall – Shuts Off Without Warning. June 14, 2011. http://www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm259078.htm[17]

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American Regent Initiates Nationwide Voluntary Recall of Methyldopate HCL Injection, USP 5 mL Single Dose Vial Due to Glass Particulates

Print Item
E–mail Item

American Regent Press Release

This recall, initiated on June 6, 2011 to the User or Consumer Level, is for Lot # 0152 only. No other lots of Methyldopate HCL Injection, USP are subject to this voluntary recall. This voluntary recall was initiated because some of the vials of this lot contained translucent visible particles consistent with glass delamination. Potential adverse events after intravenous administration of solutions containing particulates may include disruption of blood flow within small blood vessels in the lung, localized inflammation (swelling and redness), and granuloma

formation. American Regent is undertaking this voluntary recall in consideration of the potential for safety issues if this lot of Methyldopate HCL Injection, USP is administered to patients. American Regent has not received any reports of adverse events related to this recall.

Additional Information:

American Regent Press Release. American Regent Initiates Nationwide Voluntary Recall of Methyldopate HCL Injection, USP 5 mL Single Dose Vial Due to Glass Particulates. June 6, 2011.
http://www.fda.gov/Safety/Recalls/ucm258064.htm[19]

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Churchill Medical Systems, a Vygon Company, Skin-Prep Wipes Used in Convenience Kits and Trays

Print Item
E–mail Item

FDA Medical Device Recalls

The skin-prep wipes were recalled by the manufacturer due to the potential for bacterial contamination. Surgical patients, and patients who are immuno-compromised, such as those with diabetes, cancer, and certain other chronic diseases, may be at potential risk for infection. This may cause serious adverse health consequences or death.

Additional Information:

FDA Medical Device Recalls. Churchill Medical Systems, a Vygon Company, Skin-Prep Wipes Used in Convenience Kits and Tray. April 19, 2011.
http://www.fda.gov/MedicalDevices/Safety/RecallsCorrectionsRemovals/ListofRecalls/ucm259268.htm[21]

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Thermographic Imaging Systems for Breast Cancer Screening: FDA Safety Communication

Print Item
E–mail Item

FDA MedWatch Safety Alert

FDA notified consumers, women who participate in breast cancer screening and healthcare professionals that thermography is not a replacement for screening mammography and should not be used by itself to diagnose breast cancer. Thermographic systems use an infrared camera to produce images (thermograms) that show the patterns of heat and blood flow on or near the surface of the body. The FDA is not aware of any valid scientific data to show that thermographic devices, when used on their own, are an effective screening tool for any medical condition including the early detection of breast cancer or other breast disease. The FDA is concerned that women will believe these misleading claims about thermography and not receive needed mammograms. Women should have regular mammograms according to screening guidelines or as recommended by a health care provider. Patients should follow a health care

provider's recommendations for additional breast diagnostic procedure which could include thermography, clinical breast exam, breast ultrasound, MRI or biopsy.

Additional Information:

FDA MedWatch Safety Alert. Thermographic Imaging Systems for Breast Cancer Screening: FDA Safety Communication. June 2, 2011.
http://www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm257707.htm[23]

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Guide to Infection Prevention in Outpatient Settings: Minimum Expectations for Safe Care

Print Item
E–mail Item

Centers for Disease Control (CDC)

The following document is a summary guide of infection prevention recommendations for outpatient (ambulatory care) settings. The recommendations included in this document are not new but rather reflect existing evidence-based guidelines produced by the Centers for Disease Control and Prevention and the Healthcare Infection Control Practices Advisory Committee. This summary guide is based primarily upon elements of Standard Precautions and represents the minimum infection prevention expectations for safe care in ambulatory care settings. Readers are urged to consult the full guidelines for additional background, rationale, and evidence behind each recommendation. All guidelines and recommendations are available at: http://www.cdc.gov/HAI/prevent/prevent_pubs.html

Additional Information:

CDC. Guide to Infection Prevention in Outpatient Settings: Minimum Expectations for Safe Care Website. May 2011.
http://www.cdc.gov/HAI/settings/outpatient/outpatient-care-guidelines.html[25]

CDC Printable Guide to Infection Prevention in Outpatient Settings: Minimum Expectations for Safe Care. May 2011.
[26]

http://www.cdc.gov/HAI/pdfs/guidelines/Ambulatory-Care-04-2011.pdf[27]

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Reducing Alarm Hazards: Selection and Implementation of Alarm Notification Systems

Print Item
E–mail Item

Patient Safety and Quality Healthcare

Few threats to patient safety have existed for as long or been as thoroughly studied as alarm fatigue (Healthcare Technology Foundation). In December 2010, ECRI Institute listed "Alarm

Hazards" as the second highest technology hazard of 2011. Alarm hazards include inappropriate alarm modification, alarm desensitization or alarm fatigue, non-restoration of alarm settings to the normal or standard value after being modified for a specific situation, and improper relaying of alarm signals to appropriate personnel (ECRI Institute, 2010). Additionally, with the evolution of stand-alone devices to proprietary end-to-end systems, there is a proliferation of overlapping and duplicate systems. This ends up in clinicians sometimes carrying a “bandolier” of communication devices. Most alarms and other messaging are simply broadcast throughout the unit via distributed speakers and message panels.

Additional Information:

Patient Safety and Quality Healthcare. Reducing Alarm Hazards: Selection and Implementation of Alarm Notification Systems. March/April 2011.
http://www.psqh.com/marchapril-2011/799-reducing-alarm-hazards.html[29]

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A Novel Approach to Increase Residents' Involvement in Reporting Adverse Events

Print Item
E–mail Item

PubMed Abstract

In 2008-2009, the authors measured participation in adverse-event reporting by 680 residents at Oregon Health & Science University before and after implementing a quality improvement initiative, which consisted of a financial incentive and multifaceted educational campaign. The primary measure of success was an increase in the average monthly adverse-event reports submitted by residents to greater than 5% of the institution's overall report submissions. The novel approach of integrating a retirement benefit and educational campaign to increase residents' involvement in adverse-event reporting was successful. In addition to increasing residents' contributions to adverse-event reporting to levels higher than any documented in the current literature, there was also a remarkable increase in the relative frequency of near-miss reporting by residents.

Additional Information:

PubMed Abstract. A Novel Approach to Increase Residents' Involvement in Reporting Adverse Events. June 2011.
http://www.ncbi.nlm.nih.gov/pubmed/21512369[31]

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LabNet

The 2011 Joint Commission National Patient Safety Goals: Why Laboratories Need to Pay Close Attention

Print Item
E–mail Item

American Association for Clinical Chemistry (AACC) Clinical Laboratory News

Although no new goals were added in 2011 that directly relate to laboratories, significant revisions in the 2010 NPSGs that do affect laboratories were kept in place. Even if your laboratory is not accredited by JC, because of the high visibility of the NPSGs in health care today, laboratorians should at least be knowledgeable about the goals. Oftentimes, laboratorians are called upon to assist other parts of their organization that are accredited by JC. Therefore, knowing the basic thrust of the goals is valuable.

Additional Information:

AACC Clinical Laboratory News. The 2011 Joint Commission National Patient Safety Goals: Why Laboratories Need to Pay Close Attention. April 2011.
http://www.aacc.org/publications/cln/2011/April/Pages/PatientSafetyFocus_Goals.aspx[33]

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Privacy in the Era of EHRs

Print Item
E–mail Item

American Association for Clinical Chemistry (AACC) Clinical Laboratory News

As labs connect to Electronic Health Records (EHRs) within hospitals or with physician practices, they will need to lean heavily on their chief compliance officers, IT support, and other colleagues to make wise decisions about where and how lab results are delivered. Although adoption of EHRs may not advance quickly in all areas, both physicians and the public overwhelmingly agree that health IT is a key solution to healthcare quality and costs, a trend highlighted in a survey conducted by the Markle Foundation that was released in January. In the survey, approximately 80% of the public and 85% of physicians said that the government should require physicians and hospitals to share information to reduce medical errors and cut costs.

Additional Information:

AACC Clinical Laboratory News. Privacy in the Era of EHRs. March 2011.
http://www.aacc.org/publications/cln/2011/march/Pages/EHRs.aspx[35]

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HomeNet

Putting the 'patient' in patient safety: a qualitative study of consumer experiences

Print Item
E–mail Item

PubMed Abstract

Although patient safety has been studied extensively, little research has directly examined patient and family (consumer) perceptions. Evidence suggests that clinicians define safety differently from consumers, e.g. clinicians focus more on outcomes, whereas consumers may focus more on processes. Consumer perceptions of patient safety are important for several reasons. First, health-care policy leaders have been encouraging patients and families to take a proactive role in ensuring patient safety; therefore, an understanding of how patients define safety is needed. Second, consumer perceptions of safety could influence outcomes such as trust and satisfaction or compliance with treatment protocols. Finally, consumer perspectives could be an additional lens for viewing complex systems and processes for quality improvement efforts. Consumers seem acutely aware of care processes they believe pose risks to safety. Perceptual measures of patient safety and quality may help to identify areas where there are higher risks of preventable adverse events.

Additional Information:

PubMed Abstract. Putting the 'patient' in patient safety: a qualitative study of consumer experiences. May 2011.
http://www.ncbi.nlm.nih.gov/pubmed/21624026[37]

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KidNet

Oridion Medical and Philips Healthcare Microstream CO2 Filterline (FilterLine H Set Infant/Neonate, VitaLine H Set Infant/Neonate: Recall - Plastic Strands on the Adapter May Become Dislodged, Inhaled by Patient

Print Item
E–mail Item

FDA MedWatch Safety Alert

Fine plastic strands on the inner surface of the infant/neonatal airway adapter may become dislodged and inhaled by the patient. Inhalation of the plastic strands on the defective devices may cause respiratory compromise, which could result in serious illness or death. Philips instructed users to immediately identify all products from affected lots, remove them from inventory and dispose in accordance with local regulations.

Additional Information:

FDA MedWatch Safety Alert. Oridion Medical and Philips Healthcare Microstream CO2 Filterline (FilterLine H Set Infant/Neonate, VitaLine H Set Infant/Neonate: Recall-Plastic Strands on the Adapter May Become Dislodged, Inhaled by Patient. Jun 7, 2011
http://www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm258133.htm[39]

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Drugs of Abuse Tests

FDA Office of In Vitro Diagnostics

FDA regulates and reviews drugs of abuse tests before they can be sold to consumers or healthcare professionals. The information on this webpage may be helpful to anyone who performs drugs of abuse testing, i.e. parents or other consumers, as well as trained medical professionals. In addition, manufacturers of these tests may also be interested in the types of data typically submitted for FDA review.

Additional Information:

FDA Office of In Vitro Diagnostics. Drugs of Abuse Tests. June 1, 2011. http://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/InVitroDiagnostics/DrugsofAbuseTests/default.htm[41]

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Highlighted MedSun Reports

Highlighted Reports

Print Item
E–mail Item

This section contains a sample of reports from all the MedSun reports received during a particular period. The reports were submitted by MedSun Representatives. In some instances the reports have been summarized and/or edited for clarity. The entries that follow represent a cross section of device-related events submitted by MedSun reporters during the period April 1 through April 30, 2011. All other reports can be searched under the 'MedSun reports' menu pane. Note: the two month delay is due to quality control and follow-up.

ANESTHESIOLOGY

Device:
Type: Flowmeter
Manufacturer: Amvex Corporation
Brand: Dial Flowmeter
Model#: F10-2G0A3

Problem:

ECMO [Extracorporeal membrane oxygenator] sweep flowmeter was adjusted from 6 L/m [liters per minute] to 7 L/m. The flowmeter does not have a 7 L/m setting. It has settings at 6 then 8 L/m. At the in between the area there was no oxygen flow. The patient became hypoxic. The MD was notified and the oxygen device was changed. During rounds, team wanted sweep to be turned from 6 to 7. At this time bedside RN notified ECMO and proceeded to increase sweep to 7. A few minutes later sats [saturations] began to drop significantly (lowest of 12%) as well as SVO2 [Saturated Venous Oxygen] (as low as 30%). ECMO charge immediately called to bedside as well as attending MD, RT [Respiratory Therapist] and charge RN. Attending at bedside with bedside RNs assessing patient and ECMO equipment. Oxygen from wall appeared to be working at times and at others not, so ECMO flow meter attached to oxygen tank and sweep increased on dial per MD. At this time, sats began to increase as well as SVO2 [Saturated Venous Oxygen]. At this time ECMO at bedside and explained that the ECMO sweep dial turns off when dial adjusted to 7 and needs to be changed to a different flow meter to increase sweep to 7. SICU staff unaware of this information. Patient vitals returned to his norm with no apparent complications noted at this time.

Device:
Type: Pulmonary Function Testing System
Manufacturer: CareFusion Viasys Healthcare
Brand: Vmax Encore
Model#: 229

Problem:
Abrupt stopping of the treadmill occurred during Pediatric Exercise Testing. We were told by CareFusion Tech Support that CareFusion knew about this "glitch" prior to the install and training, but continued with the install and training with no prior notice to us. We were told by sales and service that the company would get back to us with an update as to the course of action CareFusion is taking to remediate this problem. Our new system has been shutdown since determining the nature of this glitch.

CARDIOVASCULAR

Device:
Type: Catheter, Intra-aortic Balloon
Manufacturer: Arrow International
Brand: Fiberoptix
Model#: IAB-05830-LWS
Lot #: KR1019018
Cat #: IAB-05830-LWS
Other #: 8 fr. 30cc

Problem:
This report is intended to document a series or trending of events rather than a specific event. Information on one catheter and patient was supplied in order to provide a sample serial and lot number for reference. There are two ongoing issues with the balloon catheter: first is that the fiber optic feature of the device frequently fails, in that the device (catheter) fails to be recognized by the console, and the physical connector for the fiber optic line falls apart. The blue slide connector which houses the tip of the fiber optic cable has literally fallen off of the catheter, so a connection to the fiber optic sensor cannot be made. The second is that the arterial line associated with the catheter, composes the secondary trigger for the balloon pump. When the fiber optics fails, the catheter clots off easily, requiring the operator to switch to the ECG leads as the only remaining trigger.

==========
Manufacturer response for Catheter, Intra-Aortic Balloon, FiberOptic: Multiple and on-going discussions with the local Arrow representative.
==========
Representative has been involved since the beginning with the concerns and has been meeting with staff and engaging them in training, education, answering questions as needed. The representative has and remains very involved in our efforts to sort out the problem.

Device:
Type: Catheter, Intravascular, Diagnostic
Manufacturer: Arrow International, Inc
Brand: Arrow Central Venous Catheterization Kit
Cat #: CDC-45703-P1A

Problem:
A physician was inserting a central line. The left chest was prepped. The vein was accessed on first attempt but wire broke (and fully retrieved). The physician said he had no trouble with a rib or clavicle. It was a smooth entry. The dilator catheter was over the wire. When the catheter was in and the physician was pulling out the wire, it wouldn't budge. He tugged a little harder. The physician said it felt tighter than it should have been. There was more resistance than you would expect. He said the outside part came off and the wire came unraveled. The physician said he has inserted multiple lines and this has never happened before or since. The packaging was not saved. The physician told staff he wanted the company notified.

Device 1:
Type: System, Magnetic Navigation, Cardiac
Manufacturer: Stereotaxis
Brand: Niobe

Device 2:
Type: Computer, Diagnostic, Programmable, Cardiac
Manufacturer: Biosense Webster

Brand: Carto 3

Device 3:
Type: Generator, Ablation, Cardiac, Rf
Manufacturer: Biosense Webster
Brand: Stockert

Device 4:
Type: Pacemaker, Implantable
Manufacturer: Medtronic Adapta
Brand: Adapta Dr
Model#: ADDR01

Problem:
The patient's dual chamber Medtronic pacemaker was set to demand pacing only mode (VVI) at rate of 40 beats per minute during a procedure using Stereotaxis Magnetic Navigation System (MNS). When the MNS system was moved into navigate position, the pacemaker went into "magnet mode" (VOO) asynchronous pacing at 85 beats per minute. To prevent complications from inappropriate pacing, the output was decreased from 2.0 V to 0.5 V (to intentionally lose capture and prevent pacing). During first application of radio frequency (RF) ablation, ECG morphology changed to what appeared to be paced beats at about 130 beats per minute at higher output. When RF ablation was terminated, the device would stop pacing and the patient's underlying tachycardia at 145 beats per minute was seen on ECG. The phenomenon was repeatedly reproduced with RF application. Grounding pad location was moved from left flank to left thigh, which intermittently resolved the issue. Medtronic rep on site was consulted, and Medtronic engineer called by telephone, but no clear cause was identified. Medtronic rep arrived in room to perform device interrogation once the MNS system was moved to stowed position. Error message on device indicated it had gone to Reset which returned device to the default factory settings of DDD (dual-chamber pacing) 60-130, output of 3.5 V. Patient's low threshold (~1.0V) allowed max tracking pacing at 130 beats per minute to capture, and her underlying tachycardia did not require pacing when off RF. Had the patient been pacemaker dependent with a threshold above 3.5V, no pacing or lack-of-capture and asystole would have occurred. Conversely, had the patient had heart failure or poor cardiac function, the rapid ventricular pacing at 130 beats per minute may have caused hemodynamic collapse. Therefore it was felt this should be reported to MedSun/HeartNet as a significant event with potential to cause harm. The pacemaker is still implanted and the patient had a good outcome.

==========
Manufacturer response for Carto 3 RMT electroanatomic mapping system, EO Medelctrophysiology recording system, Xper hemodynamic recording system, Zoll M Series defibrillator, Siemens Artis Zee fluoro system, Stereotaxis/Niobe Remote Magnetic Navigation system., Medtronic Dual Chamber Pacemaker (per site reporter)
==========
Medtronic rep here during procedure. Called technology department.

Device:
Type: System, Endovascular Graft, Aortic Aneurysm Treatment
Manufacturer: Cook
Brand: Zenith Aortic Stent Graft

Problem:
Patient presents with aortic stent graft infection. Infection was noted to be at 1 to 1 1/2 cm at the top of the bare metal stent, not near the fabric. This is extremely unusual per doctor.

GENERAL & PLASTIC SURGERY

Device:
Type: Ampule, Tissue Adhesive
Manufacturer: Ethicon
Brand: Dermabond
Lot #: CKR017

Problem:
According to directions, while crushing ampule the product splintered and broke into sharp pointed pieces. The doctor received a laceration to right index finger.

Device:
Type: Clip Applier
Manufacturer: Teleflex Medical
Brand: Hem-o-lok
Model#: 544965
Cat #: 544965

Problem:
Surgeon was using the Hem-o-lok during a cholecystectomy. He used the device to apply a self-locking plastic clip to the cystic duct. While attempting to apply a clip with the Hem-o-lok Endo applier the clips would not apply or clip. Another Hem-o-lok Endo applier was used successfully to apply the clips. There was no adverse result to the patient. When the malfunctioning applier was examined the jaws appear to be slightly out of alignment. This was not apparent without closely looking at the device. After the case, the surgeon later devised a small tool to check the alignment of the appliers before using in other cases.

Device:
Type: Clip Applier
Manufacturer: Covidien
Brand: Premium Surgiclip
Model#: S-9.0
Lot #: P1B0186

Cat #: 134046

Problem:
When going to apply a clip on the blood vessel two or more clips pushed out leaving loose metal clips in the wound, which had to be picked out. Looking back at our hospital event system this is one of six such events that have happened over the last eight months. Because of this number it was decided that these events needed to be reported. Other events included: failed to place clips properly, clip malfunction, clips did not bind and cut the colon, clip applier failed to load a clip while jaws came forward and sliced the patient's vein. Clips did not close properly. The clip applier sliced the vein when trying to apply a clip and then spit out an extra clip into the wound. All events are related to the same product number.

==========
Manufacturer response for Single Use Automatic Clip Applier, Premium Surgiclip
==========
We have not had a response back from the manufacturer to date.

Device 1:
Type: Clip Applier
Manufacturer: Covidien
Brand: Auto Suture
Model#: S-9.0
Cat #: 134046

Device 2:
Type: Clip Applier
Manufacturer: Covidien
Brand: Auto Suture
Model#: M-9.75
Cat #: 134051

Problem:
Surgeon reports that device clip delivers an inaccurate clip and has to be removed and/or replaced. This event has been reported on three occasions. In this case, the mammary artery was cut.

Device:
Type: Clip Applier
Manufacturer: Ethicon-Endo Surgery
Brand: Ligamax
Model#: EL5ML
Lot #: G4UF5P

Problem:

While performing laparoscopic cholecystectomy, clip applier was extremely hard to fire. Another unit was obtained with same problem. Another unit was then opened and still had some difficulties, notably the "handle was hard to fire, sticky".

Device:
Type: Dispersive Electrode
Manufacturer: ConMed Corporation
Brand: Macrolyte
Lot #: 1101035
Cat #: 450-2300
Other #: P/N 6859-37

Problem:
Out of three types and sizes of cautery pads, two had weight limit guidelines and one did not. This is the pad needed for our small patient. Rep [representative] was called and got answering machine. Company was called three times by RN until she was able to contact the vice pres [president] of marketing. Weight class was verified by Vice President and pad was proceeded to be used and applied by doctor. This baby girl was under general anesthesia for 1 hr 4 min while the company was trying to be reached to get the needed information.

==========
Manufacturer response for Dispersive Electrode, MacroLyte
==========
The infant was under anesthesia for 1 hr 4 min while this company was trying to be contacted. The company rep did not answer the phone either.

Device:
Type: Stapler, Skin, Absorbable
Manufacturer: Incisive Surgical, Inc.
Brand: Insorb
Model#: 2030

Problem:
Patient with no significant medical history fell, sustaining a left tibial plateau fracture with extension into the tibial shaft. The patient underwent open reduction, internal fixation of her left tibial plateau fracture with a buttress plate, and open reduction and internal fixation of the tibial shaft with periarticular plate; the wound was closed with absorbable skin staples. The patient developed multiple skin blisters, non-viable tissue and a large hematoma requiring removal of skin staples and evacuation of the hematoma with muscle flap and skin graft. Due to non-healing, patient required removal of hardware and above knee amputation.

Device:
Type: Stapler, Skin, Absorbable
Manufacturer: Incisive Surgical, Inc.
Brand: Insorb
Model#: 2030

Problem:
The patient underwent a right triathlon total knee arthroplasty with tobramycin-impregnated methyl methacrylate with a #4 right femur, #4 primary tibia with a 13 mm CS x3 insert, #32 mm symmetric patella with Stryker navigation. The skin was closed with absorbable staples. The patient was readmitted with an infected hematoma of there knee, underwent an excision of non-viable tissue, removal of multiple foreign bodies, evacuation of the hematoma, and a split thickness skin graft. The foreign bodies were discarded.

NEUROLOGY

Device:
Type: Motor, Drill
Manufacturer: The Anspach Effort, Inc.
Brand: Emax Qd8

Problem:
The surgeon was doing a translabyrinthine approach to resect a left vestibular schwannoma. An Anspach drill Emax QD8 head had been used for approximately 1 hour when the sleeve shot forward off the device like a missile. The surgeon had quick reflexes and pulled back preventing the patient from being harmed. The patient would have been seriously injured otherwise.

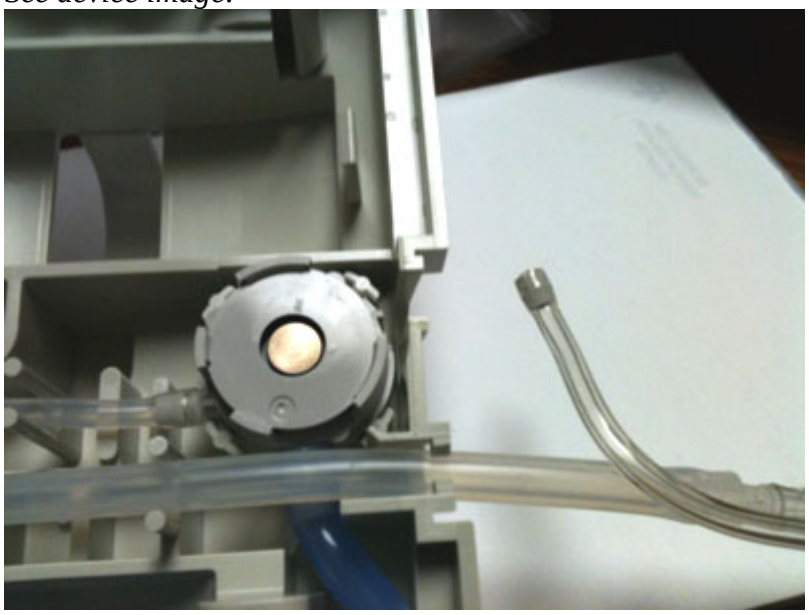
OPHTHALMIC

Device:
Type: Phaco Tubing Pack.
Manufacturer: AMO Abbott Medical Optics
Brand: Whitestar Signature Fusion Pack
Lot #: CHO1228 and CJO0095
Cat #: OPO70
Other #: AMO WhiteStar Signature Phacoemulsification machine

Problem:
Nurse was setting up and priming set; observed that tubing was not connected correctly to cassette. Examination revealed that small rigid plastic connection port was broken. Nurse requested another set which was connected properly and which primed properly. Case proceeded. Slight delay in set-up time resulted. No adverse event. Note that this event happened twice on the same day - i.e. for two separate IOL cases.

OR reports that this is a low frequency but recurring event. They estimate that this is happening about 6 times per 1000 IOL cases. Unable to determine if this is a defect in manufacturing or if this suggests a need for better in-service of staff. Digital photographs of defective device have been sent to MedSun.

See device image:



Special Note: The lollipop icon distinguishes highlighted reports that describe medical device events involving neonatal or pediatric patients, or those events involving a medical device that is indicated for use in neonatal and pediatric patient populations. FDA defines pediatric patients as less than 21 years of age.

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Medical Device Problem Summaries

Summary of MedSun Reports Describing Problems With External Defibrillation and Multifunction Electrodes

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External defibrillation and multifunction electrodes are single-use medical devices used in the emergency treatment of cardiac arrest patients. These devices are used in conjunction with compatible automatic external defibrillators (AED) or defibrillator monitors which can perform limited monitoring of a patient's ECG, delivery of defibrillation energy to a patient, and possible external pacing or cardioversion. (510(k) Summary, 2005), (510(k) Summary, 2007)

Over the past 2 years, MedSun has received 12 adverse event reports associated with the 8 devices manufactured by Kendal LTP, Philips Medical Systems, Physio-Control, and Zoll Medical. The reports were submitted by 9 hospitals between March 2009 and March 2011.

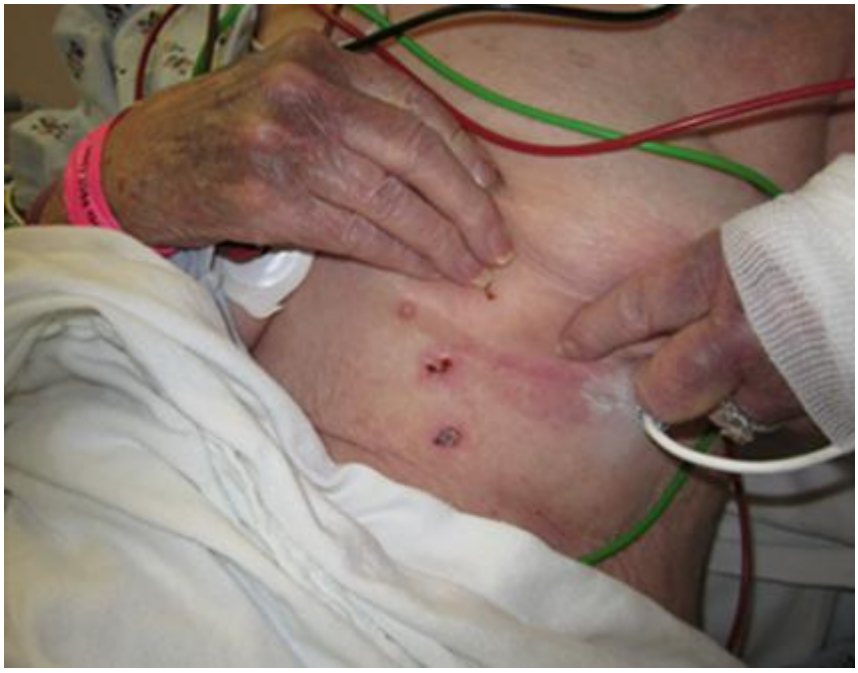
The reported device problems were:
• 2 Reports of electrode/pad not adhering to patient
• 1 Report of spark from electrode
• 1 Report of defibrillator electrode placed over ECG electrode
• 1 Report of a wire disconnection to electrode
• 1 Report of labeling of package: multifunction vs pacemaker only
• 1 Report of packaging/labeling: can not open package
• 5 Reports can not be determined from the event

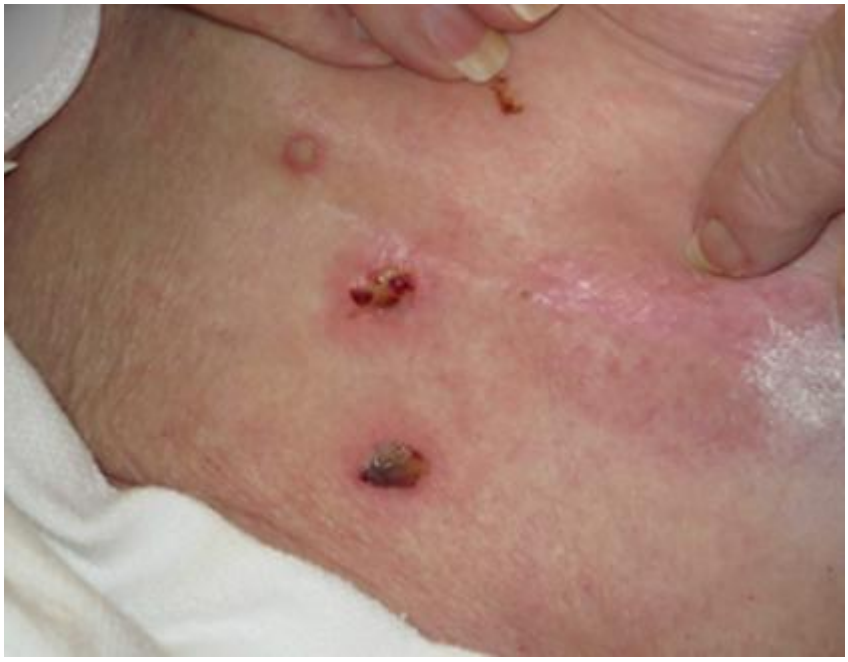
The patient problems listed below were reported in 11 of these 12 reports.
• 6 Patient burns
• 3 Possible delay in treatment
• 1 Skin breakdown
• 1 Shock to caregiver
• 1 Cannot be determined from the event

Of the reports that listed patient age, none had a patient age listed as less than 21 years and 6 had a patient age listed as greater than 21 years. Of the reports that listed patient gender, a total of 2 reports involved female patients and a total of 4 reports involved male patients.

These MedSun reports summarized above, in addition to manufacturer, healthcare, and voluntary reports contributed to FDA awareness of the device problems.

Photographs of patient burns, such as the ones described in some of the reports included in this summary appear below:





The following table lists the MedSun reports that are described in the device problem summary above.
[Note: The reports have been edited for clarity]

MedSun Reports Describing Problems with External Defibrillation and Multifunction Electrodes		
Device	**Device**	**Event Description**

Manufacturer and Brand	Identifiers (Catalog Number, Model Number, Lot Number)	
Physio Control, Inc. Quik-Combo Edge System	3010188-011, 22517, N/A	Patient burned by electrodes while connected to a Physio-Control defibrillator.
Zoll Medical Corporation One Step	8900-0214-01, 10312023, 8900-0214-01	Zoll defibrillator pads were utilized for temporary transcutaneous pacing from 15:20 hours to 19:30 hours. When the pads were removed at 09:50 on the next morning, three circle burns were noted on the patient's chest left of the sternum. The appearance of the circles was also noted on the Zoll pad. A dermatologic consultation/examination was performed on the same day the defibrillator electrodes were removed with the following conclusions: erosions, left inframammary chest. Given the well-defined appearance of these erosions this is suspicious for external-induced injury as well as char on the pacer pad, this may likely represent external injury/thermal injury due to the transcutaneous pacing. Physical examination: skin examination of the left inframammary chest revealed three small circinate well-defined erosions. There is no necrosis or gunmetal gray coloration to the lesions. Treatment will be topical with application of Vaseline to the wounds three times daily until healed. No sign of infection currently noted. The pad was saved. Manufacturer response for Electrode, Defibrillator, External, One Step: Pad was sent to the manufacturer via mail. As of today, no response from manufacturer.
Kendall-LTP Cadence MediTrace	22770PC, 28106, N/A	Our ICUs have continued to report problems with the Covidien Cadence MediTrace defib pads when placed for longer term use; since we began using this defib pad about a month ago, more than 10 events have been reported when these pads were placed in an emergency and quickly "lost contact" as the pad edges rolled off patient's skin, resulting in pads needing to be replaced before the next use. There have also been two reports of skin breakdown along the edges of the Covidien pad adhesive after these pads were removed. The maximum time these pads might be left in place by our protocol is 24 hours, however as noted we are

		receiving frequent reports that Covidien pads seem to fall off and lose contact in 2-3 hours. Health Professional's Impression: Two issues have been identified: 1) Covidien pads are insufficiently adherent in some cases. 2) Two issues of skin breakdown related to these pads. Manufacturer response for Electrode, Defibrillator, Multifunction, Cadence MediTrace: Ongoing discussion with field representative.
Meditrace, 1210H	31177721, N/A, N/A	Patient was being cardioverted. Possible spark from anterior electrode on the patient's chest noted during cardioversion, by the physician and the CRNA in attendance. Also, a burning smell was reported at this time. The electrodes were removed and new ones were applied. The patient did not have any apparent burns on the chest. Health Professional's Impression: Defibrillator was checked by the biomedical engineering department and no abnormalities were identified. Per biomedical engineering, hair was noted on the actual electrodes which may have interfered with proper contact with the patient's skin.
Kendall-LTP, MediTrace Cadence	N/A, 23215, 22770PC	Covidien Cadence defib pads are not adhering as expected. Example 1: Defibrillator pads were placed at about 11 am during a code three hours later; the posterior pad was found buckled and rolled up on the patient's back. Pads had to be replaced prior to a needed cardioversion. Several episodes reported of similar events: Event #2: Pads were placed for monitoring and potential need for pacing for the patient in a complete heart block. A few hours later the edges of the pads were noted rolling off, both the anterior and posterior pads; original pads were replaced with new pads. We routinely change pads at 24 hours. At 24 hours, the edges of these pads were again rolling off. The problem appears to be that the outer white adhesive of the pad is not adhering well to the skin. Health Professional's Impression: Pad edges are not adherent enough.
Philips Medical Systems Adult Plus	M3713A, N/A, N/A	The patient was in ventricular fibrillation. One shock was delivered via hands free patches. A few minutes after the shock was delivered, the RN was shocked when chest compressions resumed and her hands touched the defibrillation electrode pad. The EKG clip was noted to be touching the defibrillation electrode pad.

Physio-Control Inc. Quik Combo	N/A, 935802, 11996-000091	Patient was in surgery, near end of a repeat CABG operation with defibrillator electrode pads placed on the left and right sides. Patient began ventricular fibrillation, and defibrillation was attempted via the external pads 5-6 times at 200 Joule setting. Then several attempts were made using internal defibrillator paddles, which succeeded. While attempting to close the patient's chest, v-fib occurred again and several more defibrillator attempts were made using the external pads and a 360 Joule setting, until the defibrillator alarmed that the pads were not securely connected. Inspection revealed that the leadwire had separated from the left-side pad. Under the wire was a blister 5 cm long on the patient's left flank near the arm pit, with a charred region around the blister. The electrode pads were replaced with a new set. After a few more defibrillation attempts, the patient recovered, then was sent from the OR to the critical care unit where the blistered area was treated with an appropriate dressing. Patient was eventually discharged to home. The skin injury was granulating by that time and the patient's instructions were to continue keeping the area covered with a dressing. Health Professional's Impression: The broken or separated electrode wire was attributed to mechanical stresses from the patient's severe muscle contractions during repeated defibrillation attempts. Manufacturer response for Electrode, Defibrillator Pads, Quik Combo: Mfr stated that Quik Combo pads should be replaced after 25 discharges, and was unaware of problems with our lot number.
Zoll Medical Corporation Stat Padz	8900-4003, N/A, N/A	It was discovered that a patient had a minor burn after pacer pads were removed. The patient had been on an external pacer for about 24 hours and when the pacer pad was removed it was discovered that an ECG electrode, from a previous 12 lead ECG, had been left on the patient underneath the pacer pad. The burn was discovered in ICU but the pacer pads were placed in the Emergency Department. It is believed that the burn was caused by the electrode that was left on the patient unintentionally. We do not feel that the Zoll product was defective but are reporting this so others can be aware of the potential for harm. The electrode left on the patient unintentionally caused the burn.
Zoll Medical	N/A, 5209, 8900-	This lot number of pads had 4 incidents of pad burns

Corporation Pro-Padz	4005	in the EP lab. The burns were first degree with skin peel around the edge of burned area. All 4 patients had intact skin anterior and posterior prior to chest pad placement. There was no skin prep prior to placing the pads. The burns followed 2-4 defibrillations at 150 joules. Silvadene cream was applied to all burn sites. Health Professional's Impression: No problems have occurred with any other lot numbers. Manufacturer response for defibrillator adult pads, Translucent: The remaining pads from the same lot number were returned to tech support. No other problems have occurred since this lot was pulled. No answer from manufacturer yet.
Zoll Medical Corporation Pro-Padz	8900-4005, N/A, N/A	The patient was cardioverted X 3. #1. 120 joules 155.5 delivered, #2 120 joules selected 158.4 delivered, 3rd shock 200 joules selected 299.8 delivered. On the first and second shocks, the physician stated he heard a "popping sound". On the third shock he looked at patient's head and saw a "ball of fire" come out of the patient's mouth. Superficial first degree burns were noted around the rim of the anterior Zoll pad about 3 to 5 cm in length. Sivadene ointment was applied. There was no evidence of harm to mouth area. No excess metal in mouth although patient did have metal rod teeth implants. The patient had a concave chest and entire chest and arms were tattooed. The circular Zoll pad is rigid and did have to be pressed in place to adhere to the skin. The patient was successfully cardioverted and was discharged without any further problems.
ZOLL Medical Corporation Pedi-Padz	N/A, 4309 and 5009, 8900-1065 and 8900-2065	During a patient event a Zoll defibrillator was being prepped for standby. Staff needed a MULTI-FUNCTION electrode pack but inadvertently pulled a PACING ONLY electrode pack from stock. If the defibrillator had been needed and staff had not recognized the mistake by trying to plug the pad into the cable there could have been potential for patient harm. The two electrode packs look very similar with the only difference being the MULTI-FUNCTION label is tourquoise on one pack and the PACING ONLY label on the other is green. A more visible difference in the color of the two packs would have been an earlier indication of which electrode pack was needed. We were using the "multi-function cable" with the defibrillator which would require the "multi-

		function electrode cable" to work. Zoll makes a "pacing only cable" that is used with the "pacing only" electrode pack. The two (the multi-function and pacing only) cables are not interchangeable but similarly labeled
Covidien Kendall Medi-Trace Cadence Pre-Connect RTS	22770PC, 907226, N/A	The nurse opened the outer plastic package of defibrillator/pacing electrodes. She was unable to open the inner package. Scissors were used to open the package. The nurse had to cut around the machine cable that protrudes from the inner package. No patient adverse event resulted. The package is stored in temperature controlled storage rooms maintained at normal room temperature. Biomed took an unopened package and opened it. The same problem was encountered and there was difficulty getting the electrodes out of the package. However, another biomed from another facility attempted to open the package. He intuitively opened the package correctly. He just tore the tab all the way across the package despite the cable protruding through the tab. We believe that this is poorly designed packaging that should be changed and the manufacturer should emphasize proper instructions for opening the packaging. Manufacturer response (as per reporter) for pacer defibrillation pad (Pre-connect), Medi-Trace Cadence PC Manufacturer requested defective product to be returned. Since that product had already been discarded, we are sending sample of what is believed to be the same lot number.

Additional Information:

(2005). 510(k) Summary. Retrieved from [44]

http://www.accessdata.fda.gov/cdrh_docs/pdf5/K051076.pdf[45]

(2007). 510(k) Summary. Retrieved from [46]

http://www.accessdata.fda.gov/cdrh_docs/pdf7/K072812.pdf[47]